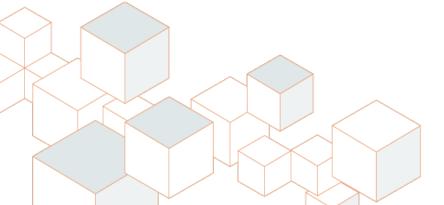


Board of Scientific Counselors. December 15, 2011

# COMMENTS ON ROC REVIEW PROCESS

**STEVE RISOTTO** 

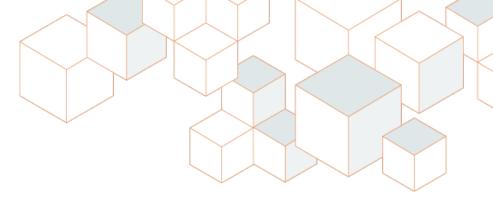




#### NTP's Proposal

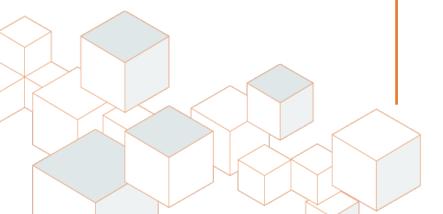
- Reduces, rather than enhances, transparency
  - Adopts a discretionary, "tailored" approach to conducting cancer evaluation
  - Denies public an opportunity to review monograph until after interagency review (NTP discretion)
  - Prevents review of interagency comments
  - Eliminates BSC review of monograph & listing recommendation (NTP discretion)
- Reduces the opportunity for meaningful public participation
  - Eliminates public comment on background document
  - Drops the requirement to respond to public comments
- Compromises the scientific integrity and rigor of the RoC process
  - Replaces background document with "concept paper"
  - Removes BSC from all but substance selection (NTP discretion)
  - Blurs science/policy earlier in the process
    - NTP develops the listing recommendation
  - Eurther insulates NTP & RoC reviewers from scientific debate

## Clarification of Listing Criteria



Revise the listing criteria as applied to "known" carcinogens to include the requirement for -

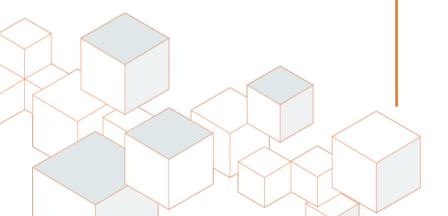
- a biologically plausible mechanism,
- an assessment of the quality of the study, or studies, on which the determination is based
- a weight-of-evidence evaluation of all the available information



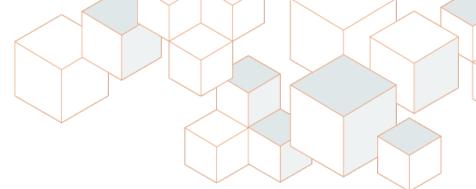
### Focus on Scientific Decision-Making



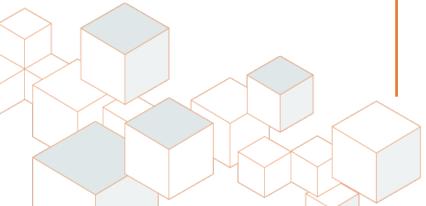
- Employ a consistent weight-ofevidence framework
  - formulated upon a hypothesis-based, mode-of-action evaluation
  - data from all relevant studies can be systematically reviewed and given appropriate weight
- Incorporate a standardized approach to evaluating studies
  - such as that recommended by the National Academy of Sciences



#### **Review Process**



- Conduct an independent peer review
  - Expert panel selected by a transparent process (e.g., NAS panel selection process)
  - Ensure appropriate level & breadth of expertise
- Provide a summary of the main points of controversy
- Allow panel to make the listing recommendation
  - Not NTP
  - Recommendation based on objective and transparent criteria



### Public Review & Comment



- Allow for public comment at each stage of the review process, including -
  - selection of substances
  - draft monograph (w/o listing recommendation)
  - revised draft monograph
  - final draft monograph
- Prepare a response to comments at each stage

